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510(k) Summary for K130872

JAN 30 2014

SUBMITTED BY:

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DATE PREPARED: January 14, 2014

TRADE NAME: CardioCel®

COMMON NAME: Intracardiac Patch

CLASSIFICATION NAME: Intracardiac Patch or Pledget
(21 CFR 870.3470; Product Code DXZ)

PREDICATE DEVICE(S): Edwards Bovine Pericardial Patch (K082139)
CV Peri-Guard Cardiovascular Patch (K971726)

DEVICE DESCRIPTION:

The CardioCel device is a cardiovascular patch prepared from glutaraldehyde-crosslinked bovine pericardium using the ADAPT® TEP technology. It is a sterile, light yellow to beige colored, moist, pre-cut, flat sheet of acellular collagen.

CardioCel has a shelf life of 24 months when stored between 2°C - 25°C.

CardioCel is supplied in three sizes: 4 x 4 cm, 5 x 8 cm and 14 x 7 cm.

INDICATIONS FOR USE:
CardioCel is indicated for use as a patch in pericardial closure and the repair of cardiac and vascular defects including intracardiac defects; septal defects, valve and annulus repair; great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing.

COMPARATIVE ANALYSIS:
CardioCel is manufactured from glutaraldehyde crosslinked bovine pericardium, which is the same material used for the predicate devices. CardioCel is considered to be substantially equivalent to the predicates for the following reasons:

- Same raw material.
- Same intended use.
- Used in the same patient population.
- Used in the same clinical environment.
- Manufactured using the same principles of crosslinking with glutaraldehyde.
- Used in the same anatomical region (cardiovascular system).
- Intended to perform as a long term implant, maintaining the integrity of the area repaired.
- Operates using the same fundamental scientific technology.
- Supplied in several sizes.
- Similar manufacturing process
- Similar sterilisation method to one predicate.
- Similar packaging and labeling.

Please see Table 1 for a comparison of CardioCel to the Edwards Bovine Pericardial Patch (K082139) and the CV Peri-Guard Cardiovascular Patch (K971726).

The safety and effectiveness of glutaraldehyde-crosslinked bovine pericardium patches for cardiovascular reconstruction and repair is well established. Cardiovascular patches have proved to be effective in achieving the desired results and are well tolerated by the host tissue.

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SUBSTANTIAL EQUIVALENCE INFORMATION:

Bench testing

CardioCel functional testing including burst strength, suture retention strength, tensile strength, crosslink stability and pronase digestion testing has demonstrated that CardioCel is a consistent, stable patch material suitable for cardiovascular repair in high pressure environments. Side by side studies of burst strength, crosslink stability and pronase digestion have demonstrated that CardioCel is substantially equivalent the predicate devices.

Biocompatibility

The biocompatibility of gluraldehyde-crosslinked bovine pericardium patches is well-established by a long history of clinical use in cardiovascular applications. Biocompatibility testing according to the requirements of ISO 10993 confirmed that CardioCel exhibited favorable biocompatibility characteristics in common with the predicate devices.

Non-clinical studies

CardioCel has been evaluated in small and large animal models for biocompatibility, safety and performance. Pivotal studies in sheep models demonstrated that CardioCel provided effective and durable repair of jugular vein defects and both mitral and pulmonary heart valve defects. The biocompatible properties of CardioCel allowed tissue remodeling in and around the implant and preservation of valve function without calcification. The safety and performance characteristics of CardioCel in a high pressure hemodynamic environment compare favorably with published animal studies using predicate devices.

Clinical studies

A clinical study of 30 pediatric patients requiring surgical repair of a range of congenital cardiac anomalies was undertaken to assess the safety and efficacy of CardioCel as an intracardiac repair patch. CardioCel showed durability, efficacy and favorable hemodynamic properties. There was no graft related morbidity or mortality and no evidence of calcification up to 36 months after surgery. The clinical performance of CardioCel compares favorably with clinical studies using predicate devices.

Information from bench testing, biocompatibility testing, non-clinical studies and clinical studies support the claim that CardioCel cardiovascular patch is substantially equivalent to marketed devices including the Edwards Bovine Pericardial Patch (K082139) and the CV Peri-Guard Cardiovascular Patch (K971726).

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Table 1: Comparison of CardioCel with Edwards Bovine Pericardial Patch and CV Peri-Guard™ Cardiovascular Patch.

	CardioCel	**Edwards Bovine Pericardial Patch**	**CV Peri-Guard™ Cardiovascular Patch**
Regulatory Class	II	II	II
510(k) number	K130872	K082139	K971726
Classification Name	Intracardiac Patch or Pledget	Intracardiac Patch or Pledget	Intracardiac Patch or Pledget
CFR Section	870.3470	870.3470	870.3470
Product Code and Classification Panel	DXZ – Panel 74	DXZ – Panel 74	DXZ – Panel 74
Device Name	CardioCel	Edwards Bovine Pericardial Patch with XenoLogiX Treatment	CV Peri-Guard™ Cardiovascular Patch
Trade/Common Name	CardioCel	Edwards Bovine Pericardial Patch	Cardiovascular Patch
Manufacturer	Admedus Pty Ltd	Edwards LifeSciences LLC	Bio-Vascular Inc.
Description	The CardioCel device is a cardiovascular patch prepared from bovine pericardium using the ADAPT® TEP technology. It is a sterile, light yellow to beige colored, moist, pre-cut, flat sheet of acellular collagen and is supplied in three sizes: 4 x 4 cm, 5 x 8 cm and 14 x 7 cm, which may be tailored to size during surgery.	The Edwards Bovine Pericardial Patch is comprised of a rectangular sheet of bovine pericardium that has been preserved in a buffered glutaraldehyde solution. The pericardial patch is in the form of a 10 cm x 15 cm size, and may be tailored during surgery to meet the specific configuration needs of individual circumstances.	CV Peri-guard is composed of bovine pericardium, cross-linked with glutaraldehyde. Available in configurations ranging from 1 cm x 1 cm to 14 cm x 16 cm.
Intended Use	For closure following open-heart surgery; intracardiac defects; septal defects and annulus repairs; cardiac and vascular reconstruction and repairs; peripheral vascular reconstruction and repairs; great vessel reconstruction and repairs; and suture-line buttressing.	To assist in closure following open-heart surgery; intracardiac defects; septal defects and annulus repairs; cardiac and vascular reconstruction and repairs; peripheral vascular reconstruction and repairs; great vessel reconstruction and repairs; and suture-line buttressing.	May be used for repair of ventricular septal defect (VSD) using either a single patch or reinforced patch technique. May also be used in other applications exposed to peak systolic pressure using a reinforced patch technique (i.e. ventricular aneurysm patch, aortic graft suture line buttress).

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	CardioCel	Edwards Bovine Pericardial Patch	CV Peri-Guard™ Cardiovascular Patch
Indications for use	CardioCel is indicated for use in pericardial closure and the repair of cardiac and vascular defects including intracardiac defects; septal defects, valve and annulus repair; great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing.	The Edwards Bovine Pericardial Patch is indicated for use as a surgical patch material for augmenting the patient's own pericardium to assist in closure following open-heart surgery; intracardiac defects; septal defects and annulus repairs; cardiac and vascular reconstruction and repairs; peripheral vascular reconstruction and repairs; great vessel reconstruction and repairs; and suture-line buttressing.	CV Peri-guard is indicated for use as a patch for intracardiac defects, great vessel, valve repair and suture line buttressing (i.e. atrial septal defect (ASD) patch, atrial patch, aortic patch, valve annuloplasty, coronary graft buttress).
Intended population	Patients with intracardiac and cardiovascular defects requiring repair (paediatric and adult groups)	Patients with intracardiac and cardiovascular defects requiring repair (paediatric and adult groups)	Patients with intracardiac and cardiovascular defects requiring repair (paediatric and adult groups)
Clinical setting	In-hospital (bioimplant surgical implanted during open heart surgery)	In-hospital (bioimplant surgical implanted during open heart surgery)	In-hospital (bioimplant surgical implanted during open heart surgery)
Anatomical sites	Cardiovascular	Cardiovascular	Cardiovascular
Materials	Bovine pericardium	Bovine pericardium	Bovine pericardium
Design and scientific principles	Glutaraldehyde fixed bovine pericardium	Glutaraldehyde fixed bovine pericardium	Glutaraldehyde fixed bovine pericardium
Performance	A long term implant for the repair of cardiovascular defects	A long term implant for the repair of cardiovascular defects	A long term implant for the repair of cardiovascular defects
Sterilization method	Sterilised using propylene oxide	Sterilised using formalin-glutaraldehyde	Sterilised using ethanol and propylene oxide
Biocompatibility	Biocompatible; meeting the requirements of ISO 10993	Biocompatible; meeting the requirements of ISO 10993	Biocompatible; meeting the requirements of ISO 10993

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 30, 2014

Admedus Regen Pty Ltd
Christopher Sloan
1801 Rockville Pike, Suite 300
Rockville, MD 20852

Re: K130872
Trade/Device Name: CardioCel
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.
Regulatory Class: Class II
Product Code: DXZ
Dated: December 30, 2013
Received: December 30, 2013

Dear Christopher Sloan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director,
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K130872

Device Name: CardioCel®

Indication For Use: CardioCel is indicated for use as a patch in pericardial closure and the repair of cardiac and vascular defects including intracardiac defects; septal defects, valve and annulus repair; great vessel reconstruction, peripheral vascular reconstruction and suture line buttressing.

Prescription Use __X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C))

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Melissa A. Torres -S Date: 2014.01.30 22:08:22 -05'00'